Remarks

The specification has been amended to properly recite trademarks appearing therein.

Claims 12-19 and 37-52 were previously pending in this application. Claims 12, 19 and 37 have been amended to be consistent with the Group election and/or to correct claim dependency. Claim 47 has been amended to correct typographical errors. Claims 12-19 and 37-52 are now pending.

No new matter has been added.

Restriction Requirement

The Examiner has acknowledged Applicant's election of Group I, claims 12-19 and 37-52 and species elections of a CpG nucleic acid, a down-regulator of IgE that is itself an anti-Ig antibody or a fragment thereof, and an asthma medicament that is bronchodilator/beta-2 agonist salbutamol.

The Examiner states that claims 19, 37, 41, 43, 46 and 49-51 have been withdrawn from consideration as being drawn to non-elected species. The Examiner further requests that these claims be either cancelled or amended to remove the non-elected species. Applicant respectfully disagrees. Applicant reiterates that the species elections were made for searching purposes only. 37 CFR § 1.142(b) relates to non-elected *inventions*, not non-elected *species*, as asserted by the Examiner. As stated in the Restriction Requirement, "Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is *finally* held to be allowable ... (and) ... upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form ... " (emphasis added). Thus, Applicant respectfully reminds the Examiner that there is no requirement for cancellation or amendment of the affected claims as they may be considered until a final determination on the generic claim is made.

Rejection under 35 U.S.C. § 112

Claims 12-18, 38-40, 42, 44, 45, 47, 48 and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 12-18 are rejected due to the recitation of hypo-responsive subject and refractory subject. The specification at page 47, lines 5-24 defines a hypo-responsive subject as one who has previously failed to respond to a treatment directed at treating or preventing asthma or allergy or one who is at risk of not responding to such treatment. The treatment may be an asthma/allergy treatment and the subject is then hypo-responsive to an asthma/allergy treatment. The same section of the specification teaches that hypo-responsive subjects include those refractory to an asthma/allergy medicament. "Refractory" is defined as resistant or failure to yield to treatment. Refractory subjects have received treatment before and either did not respond (i.e., non-responders) or did at one time respond but now no longer respond to such treatment. Hypo-responsive subjects also include elderly subjects, regardless of whether they have or have not previously received treatment as such subjects are at risk of not responding.

Accordingly, a refractory subject is one type of hypo-responsive subject. Thus, while these terms overlap, they are nevertheless defined in the specification and their meaning in the claims is therefore clear and definite. The requirements of 35 U.S.C. § 112, second paragraph, are therefore satisfied.

Claims 38-40, 42, 44, 45, 47, 48 and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner has rejected these claims because it is unclear to the Examiner why one would administer an asthma/allergy medicament to a subject that is hypo-responsive to such a medicament. The Examiner is respectfully reminded 35 U.S.C. § 112, second paragraph, requires that the claims be definite so that the metes and bounds of protection sought by Applicant be known to the public. Keeping that in mind, the invention relates to the administration of an immunostimulatory nucleic acid to a hypo-responsive subject. The subject may also receive an asthma/allergy medicament, optionally in sub-therapeutic doses, where the immunostimulatory nucleic acid renders the subject responsive to the medicament. With respect to the use of sub-therapeutic doses of the medicament, it is contemplated that when the subject receives the immunostimulatory nucleic acid, the asthma/allergy medicament dose may be lowered for example to reduce side-effects thereof. See page 6, line 25-31 and page 71, lines 13-20.

Accordingly, the combined use of an immunostimulatory nucleic acid and an allergy/asthma medicament and the claims reciting this limitation are clear and definite. The requirements of 35 U.S.C. § 112, second paragraph, are therefore satisfied.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 12-18 are rejected under 35 U.S.C. § 102 as being anticipated by Kline et al. (1997), Broide et al. (1999), Krieg et al. (WO98/18810), Krieg et al. (US 6,214,806), Davis et al. (US 6,406,705), Raz (US 6,498,148) and Sur et al. (1999). At the outset Applicant respectfully points out that they previously rebutted rejection of the claims in view of many of these references on the basis that none of the cited references teaches hypo-responsive subjects. The Examiner is directed to Applicant's response filed March 25, 2004 for rebuttal of Kline et al. (1997), Broide et al. (1999), Krieg et al. (WO98/18810), Krieg et al. (US 6,214,806), Davis et al. (US 6,406,705) and Raz (US 6,498,148). In response, the Examiner states that "it would appear that the prior art discloses such subjects" without any supporting evidence for this statement. None of the characterization of the references provided by the Examiner supports this statement either. Applicant maintains that the previously cited references do not teach these subject types and respectfully requests that the Examiner specifically point out where such teaching exists in these references. Absent this showing, the Examiner has not met her burden under 35 U.S.C. § 102.

The Examiner is directed to Applicant's response filed March 25, 2004 for rebuttal of the rejections in view of Kline et al. (1997), Broide et al. (1999), Krieg et al. (WO98/18810), Krieg et al. (US 6,214,806), Davis et al. (US 6,406,705) and Raz (US 6,498,148).

Claims 12-14 and 18 are rejected under 35 U.S.C. § 102(a) as being anticipated by Sur et al., 1999 (J. Immunology, 1999, 162/10:6284-6293).

Sur et al. does not disclose hypo-responsive subjects, as recited in claims 12-18, and it therefore cannot anticipate these claims.

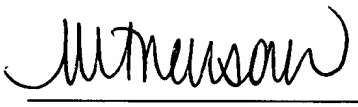
Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

A Notice of Allowance is respectfully requested. **If this communication does not place the case in condition for allowance, Applicant's representative requests a telephone interview with the Examiner prior to the issuance of a further action.**

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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